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| APPLICATION NO | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO | CONFIRMATION NO |
|----------------|-------------|----------------------|--------------------|-----------------|
| 09 903,395 | 07 10 2001 | Keith D. Allen | R-653 | 9465 |

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DELTAGEN, INC.
1003 Hamilton Avenue
Menlo Park, CA 94025

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| EXAMINER |
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WILSON, MICHAEL C

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| ART UNIT | PAPER NUMBER |
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1632

DATE MAILED: 04 16 2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/903,395

Applicant(s)

ALLEN, KEITH D

Examiner

Michael C. Wilson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2002.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-33 and 35-37 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

4) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 4) ☐ Interview Summary (PTO-413, Paper No. 1)
- 5) ☐ Notice of Informal Patent Application (PTO-152)

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DETAILED ACTION

The amendment filed 11-7-02, paper number 8, requesting replacement of Fig. 2A has not been entered. The amendment was not entered because a marked up version of the changes to Fig. 2A was not provided.

The amendment filed 12-11-02, paper number 10, has entered in part. The amendment to pg 8, lines 12-15, and the amendment to Fig. 2A have been entered.

Sequence Listing

The application is in sequence compliance.

Election/Restrictions

Claim 34 has not been considered because it is unclear. Determining whether an agent modulates an abnormal spleen, thymus or lymph node using cells as claimed in the absence of an animal does not make sense. As such, a determination as to what group claim 36 belongs cannot be made. Therefore, claim 36 has been excluded from consideration in the restriction requirement.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I, claims 1-4, drawn to a construct encoding two nucleic acid sequences homologous to a melanocortin-3 receptor gene and a selectable marker, classified in class 435, subclass 320.1

Group II, claims 5-7, 9, 13-15, 29 and 33, drawn to cells transfected with a vector
selectable marker, cells having a disruption in a melanocortin-3 receptor gene, cells isolated from

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a mouse having a disruption in a melanocortin-3 receptor gene, and ES cells having a disruption in a melanocortin-3 receptor gene, methods of using such cells to test agents, classified in class 435, subclass 325.

Group III, claims 8, 11, 12, 17-26, 28 and 30-32, drawn to a transgenic mouse having a disruption in a melanocortin-3 receptor gene and a method of making such a mouse, classified in class 800, subclass 8.

Group IV, claims 10 and 27, drawn to a method of making transgenics having a disruption in a melanocortin-3 receptor gene, classified in class 800, subclass 21.

Group V, claims 16, 35 and 36, drawn to an agonist of a melanocortin-3 receptor, classified in various classes and subclasses.

Group VI, claims 16, 35 and 36, drawn to an antagonist of a melanocortin-3 receptor, classified in various classes and subclasses.

Group VII, claim 37, drawn to data, classified in various classes and subclasses.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct because the cells of group II can be used to test cells *in vitro* while the construct can be used to make a probe. The cells do not require the construct and the construct does not have to be used to make the cells as they may occur naturally or by other means of mutagenesis. In addition, the construct does not necessarily disrupt a melanocortin-3 receptor gene because it encodes at least two sequences that are

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Inventions I and III are patentably distinct because the mouse of group III can be used as a model of disease while the construct can be used to transfect cells in vitro. The mouse does not require the construct and the construct do not have to be used to make the mouse. In addition, the construct does not necessarily disrupt a melanocortin-3 receptor gene because it encodes at least two sequences that are homologous to a melanocortin-3 receptor gene.

Inventions I and IV are patentably distinct because the construct can be used to make a probe while the method is used to make a disease model. The products and reagents required for a construct are materially distinct from those required to make a transgenic. Inserting the construct of claim 1 into a cell does not necessarily result in a disruption in the melanocortin-3 receptor gene in claim 10. The construct of claim 1 encompasses a construct encoding the full-length gene. The method of claim 10 does not require disruption occurs. The burden required to search both groups together would be undue.

Inventions I and V or VI are patentably distinct because the construct can be used to make melanocortin-3 receptor or to disrupt a melanocortin-3 receptor gene while modulators of melanocortin-3 receptor can be used to treat disease. The protocols and reagents for constructs and modulators are materially distinct and separate. The construct does not require the modulators and the modulators do not require the construct.

Inventions I and VII are patentably distinct because the construct can be used to make a probe while the data can be used for statistical analysis. The protocols and reagents for constructs and data obtained from transgenic mice are materially distinct and separate. The

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Inventions II and III are patentably distinct because the mouse of Group III can be used as a model of disease while the cells can be used to isolate protein *in vitro*. The mouse does not have to be made using a transfected cell or an ES cell as it may occur in nature. A cell comprising the construct may not disrupt a melanocortin-3 receptor gene because the construct does not necessarily disrupt a melanocortin-3 receptor gene.

Inventions II and IV are patentably distinct because the cells can be used to test compounds *in vitro* while the method is used to make an animal. The products and reagents required for the cells are materially distinct from those required to make a transgenic. Inserting the construct of claim 1 into a cell does not necessarily result in a disruption in the melanocortin-3 receptor gene because the construct of claim 1 encompasses a construct encoding the full-length gene. The method of claim 10 does not require disruption occurs. The burden required to search both groups together would be undue.

Inventions II and V or VI are patentably distinct because the cells can be used to study the function of melanocortin-3 receptor while the melanocortin-3 receptor modulators can be used to treat disease. The protocols and reagents for cells and modulators are materially distinct and separate. The cells do not require the modulators and the modulators do not require the cells.

Inventions II and VII are patentably distinct because the cells can be used to test compounds while the data can be used for statistical analysis. The protocols and reagents for transgenic mice and data obtained from transgenic mice are materially distinct and separate. The

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Inventions III and IV are patentably distinct because the mouse can be used to make cells for an *in vitro* assay while the method is used to make an animal. The products and reagents required for the using the transgenic are materially distinct from those required to make a transgenic. The burden required to search both groups together would be undue.

Inventions III and V or VI are patentably distinct because the mouse can be used as a model of disease while the modulator of melanocortin-3 receptor can be used to treat a patient. The protocols and reagents for mice and for using a modulator to treat disease are materially distinct and separate. The mouse does not require the modulator and the modulator does not require the mouse.

Inventions III and VII are patentably distinct because the mouse can be used as a model of disease while the data can be used for statistical analysis. The protocols and reagents for transgenic mice and data obtained from transgenic mice are materially distinct and separate. The mouse does not require the data and the data does not require the mouse.

Inventions IV and V or VI are patentably distinct because the method can be used make a transgenic while the modulator of melanocortin-3 receptor can be used to treat a patient. The protocols and reagents for making transgenics and for using a modulator to treat disease are materially distinct and separate. The method does not require the modulator and the modulator does not require the method.

Inventions IV and VII are patentably distinct because the method is used to make a mouse while the data can be used for statistical analysis. The protocols and reagents for making

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The method of making the mouse does not require the data and the data does not require the method of making the mouse.

Inventions V and VI are patentably distinct because antagonists and agonists have different modes of operations, different purposes and different structures. The antagonist does not require the agonist and vice versa. The burden required to search both groups together would be undue.

Inventions V or VI and VII are patentably distinct because the modulator can be used to treat disease while the data can be used for statistical analysis. The protocols and reagents for using modulators and for data obtained from transgenic mice are materially distinct and separate. The modulators do not require the data and the data does not require the modulators.

Because these inventions are distinct for the reasons given above and the search required for each of the groups is mutually exclusive, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.


Questions of formal matters can be directed to the patent analyst, Dianiece Jacobs, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-3388.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson



**MICHAEL WILSON
PRIMARY EXAMINER**